

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2014.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-430

Trade Name: Stafac® and Coban®
Ingredients: Virginiamycin and monensin
Sponsor: Phibro Animal Health Corp.
Approval Date: September 8, 2014
Status: OTC
Route: Oral, in feed
Species: Chickens (broilers)
Drug Form: Type A medicated articles
Concentration: Virginiamycin -20 g per ton of feed
Monensin -90 to 110 g per ton of feed
Indications: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

ANADA Number: 200-540

Trade Name: Meloxicam Solution for Injection
Pioneer: Metacam® 5 mg/mL Solution for Injection
Ingredients: Meloxicam
Sponsor: Putney, Inc.
Approval Date: September 21, 2014
Status: Rx
Route: Dogs: Subcutaneous or intravenous injection
Cats: Subcutaneous injection
Species: Dogs and cats
Drug Form: Sterile solution
Concentration: 5 mg/mL
Indications: **Dogs:** For the control of pain and inflammation associated with osteoarthritis.
Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery.

Suitability Petitions

Number: 13-P-1511-001

Petitioner: PetaStrip, LLC
Date Filed: November 7, 2013
Action: Denied
Action Date: January 31, 2014
Description: The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD for Cats, sponsored by Merial Ltd. under NADA 141-078. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.

Number: 13-P-1512-001

Petitioner: PetaStrip, LLC
Date Filed: November 7, 2013
Action: Denied

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The following corrections or additions to the list were completed in September 2014.

Action Date: January 31, 2014
Description: The petitioner requests to file an ANADA for a generic ivermectin that differs from the pioneer product, HEARTGUARD Chewables for Dogs, sponsored by Merial Ltd. under NADA 140-886. The generic product will differ in dosage form. The RLNAD is approved as a soft chewable tablet. The proposed dosage form is an ivermectin impregnated soluble oral thin film.

Number: 14-P-0748-0001

Petitioner: Piedmont Animal Health
Date Filed: June 2, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requests to file an ANADA for a generic milbemycin oxime that differs from the pioneer product, INTERCEPTOR FLAVOR TABS, sponsored by Novartis Animal Health US, Inc under NADA 140-915. The generic product will differ in dosage form. The RLNAD is approved as a hard compressed tablet. The proposed dosage form is a soft chewable tablet.

Number: 14-P-0772-0001

Petitioner: Piedmont Animal Health
Date Filed: June 6, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requests to file an ANADA for a generic pimobendan that differs from the pioneer product, VETMEDIN Chewable Tablets, sponsored by Boehringer Ingelheim Vetmedica, Inc. under NADA 141-273. The generic product will differ in dosage form. The RLNAD is approved as a compressed, hard, chewable tablet. The proposed dosage form is a soft chewable tablet.

Number: 14-P-0794-0001

Petitioner: e5 Pharma, LLC.
Date Filed: June 12, 2014
Action: Approved
Action Date: August 26, 2014
Description: The petitioner requests to file an ANADA for a generic methimazole that differs from the pioneer product, FELIMAZOLE, sponsored by Dechra, Ltd under NADA 141-292. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet. The proposed dosage form is a soft chewable tablet.